

NAPM



NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS

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March 8, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. 95D-1268 - Guidance for Industry: Variations in Drug Products that May Be Included in a Single ANDA

The National Association of Pharmaceutical Manufacturers (NAPM) appreciates the opportunity to comment on the document, "Guidance for Industry: Variations in Drug Products that May Be Included in a Single ANDA" [Docket No. 95D-1268]. These comments represent the consensus of leading domestic and international manufacturers of bulk active pharmaceuticals and generic drug products.

We are very pleased that the Agency has produced a guidance that is intended to reduce the burden on industry for submitting and maintaining separate applications for certain variations of the same drug product. NAPM fully agrees with the Agency for the need to reduce the burden of unnecessary paperwork on the industry.

NAPM is the national trade organization representing manufacturers, distributors and repackagers of generic multisource prescription drugs, OTC drugs, dietary supplements and veterinary drugs. The organization prides itself in serving the needs of its members and has been heavily involved in legislative, legal, regulatory and technical issues.

We thank you for the opportunity to submit our comments. We hope that our comments are clear and welcome any questions that you may have.

Sincerely,

Leon Shargel
Leon Shargel, Ph.D.
Vice President and Technical Director

cc: Doug Sporn

98D-1268

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**GUIDANCE FOR INDUSTRY
VARIATIONS IN DRUG PRODUCTS
THAT MAY BE INCLUDED IN A SINGLE ANDA
DOCKET NO. 95D-1268**

Comments:

NAPM has found several sections of this document that needs further clarification.

p. 4, III.A. Table, "Solid Oral Dosage Forms"

We feel that applications submitted at different times for different strengths of the same drug product should be filed as a separate ANDA. For example, the first ANDA submission has been reviewed and has received tentative FDA approval. However, at a later time, another ANDA application is submitted for a different strength of the same product. The FDA should not hold up approval of the first ANDA when reviewing the application for a different strength of the same product. Thus, we feel that if an ANDA is pending, the manufacturer should have a separate ANDA for an additional strength.

FDA regards different strengths as different drug products for purposes of 180-day exclusivity. Treating a subsequent submission for a different strength as a separate ANDA would simplify procedures as a related to Paragraph IV certifications, tentative and final approval dates, and 180 day exclusivity.

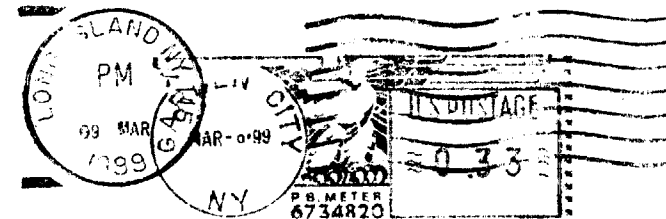
The Table "Solid Oral Dosage Forms" is somewhat confusing. For example, is more than one ANDA needed for applications with different color and shape for multiple strengths?

p. 6, III.C. Transdermal Products

NAPM does not understand the Agency's rationale for requiring different ANDA applications for different manufacturing procedures and controls.

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